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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,393	11/02/2001	Charles Jack Fisher	X-12444A	8106

25885 7590 04/09/2003

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PATENT DIVISION
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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	5

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,393	FISHER ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The disclosure is objected to because of the following informalities: At page 2, line 16, the letter characters on either side of "endotoxin" should be deleted. At page 3, line 6, "endotoxin" is misspelled. At page 4, line 10, "bactericidal" is misspelled. At page 10, line 36, "aerosolized" is misspelled. The photocopied handwritten corrections present in the instant specification are not an acceptable format for corrections. Appropriate correction is required.

2. Claims 16-32 are objected to because of the following informalities: At claim 16, line 4, "bactericidal" is misspelled. Appropriate correction is required.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 16-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,344,197. Although the conflicting claims are not identical, they are not patentably distinct from each other. The '197 patent does not claim a human activated protein C which is recombinant in origin, does not claim achieving protein C plasma ranges of about 30 ng/ml to about 150 ng/ml, and does not claim intermittent injection of the BPI protein. It would have been obvious to one of ordinary skill in the art to use recombinant human activated protein C as the source of the human activated protein C required by the claimed method of the '197 patent because recombinant

sources are known, safe, and readily available sources of proteins. It would have been obvious to one of ordinary skill in the art to optimize the dosage of the human activated protein C in the claimed method of the '197 patent, and thereby to optimize the blood levels of the active agent, because dosage is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts. It would have been obvious to one of ordinary skill in the art in the claimed method of the '197 patent to determine all operable and optimal administration schedules for the BPI protein because administration schedules are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts.

5. Claims 16-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,008,199 in view of Lawrence et al. The '199 patent claims treating human patients with an acquired hypercoagulable state, such as sepsis, with activated Protein C at a dosage rate preferably of about 24 μg/kg/hr for about 24 to about 144 hours. Initial administration can be by bolus injection followed by continuous infusion. The '199 patent does not claim an activated protein C which is a recombinant human activated protein C. It would have been obvious to one of ordinary skill in the art to use recombinant human activated protein C as the source of the activated protein C required by the claimed method of the '199 patent because use of the human variant will reduce the possibility of immunological reactions, and because recombinant sources are known, safe, and readily available sources of proteins. The '199 patent does not claim co-administering a BPI protein with the activated protein C. Lawrence et al teach treating Gram-negative bacteremia or septic shock in human patients by administering a combination of a polyclonal immunoglobulin against Gram-negative bacterial endotoxins and protein C. The

protein C can be either in its zymogen form or in its activated form. The immunoglobulins and the protein C can be administered either together or separately. The immunoglobulins and the protein C can be administered parenterally, e.g., intravenously, intramuscularly, or intraperitoneally, and the dosages can vary, depending upon disease severity, the status of the patient's hemostatic and fibrinolytic systems, and the use of other active agents. See, e.g., the Abstract; column 4, lines 42-48; and column 5, line 53 - column 6, line 14. The immunoglobulins of Lawrence et al correspond to Applicants' claimed BPI protein. In the specification, Applicants have defined "BPI protein" as embracing polypeptide variants of BPI protein, analogs of BPI protein, and variants of analogs of BPI protein (see, e.g., page 6, lines 30-37, and page 9, lines 13-29) and emphasize that BPI protein need not have the same or similar amino acid sequence as a natural human BPI protein (see page 9, lines 30-33). At page 2, lines 13-17, of the specification, Applicants state that BPI is capable of binding to and neutralizing lipopolysaccharide/endotoxin, which is the same function exhibited by the immunoglobulins of Lawrence et al. Accordingly, the immunoglobulins of Lawrence et al are deemed to constitute "BPI proteins" as the term is defined by Applicants. It would have been obvious to one of ordinary skill in the art to co-administer the immunoglobulins of Lawrence et al with the activated protein C claimed by the '199 patent because Lawrence et al teach that co-administration of the immunoglobulins would be effective in treating the underlying infection causing the septic shock. It would have been obvious to one of ordinary skill in the art in the claimed method of the '199 patent as modified above by Lawrence et al to determine all operable and optimal dosages and administration schedules for the co-administered immunoglobulins because dosages and administration schedules are art-recognized result-effective variables which

are routinely determined and optimized in the pharmaceutical arts, and because Lawrence et al teach the need to optimize dosages and administration schedules depending upon the particular patient being treated.

6. Claims 16-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,008,199 in view of Lawrence et al, Friedmann et al, and Scott '739. Lawrence et al, as applied in the above obviousness-type double patenting rejection, teach administration of an immunoglobulin which binds to and neutralizes lipopolysaccharide/endotoxin, but do not teach administration of BPI which has the same function. Friedman et al disclose treating humans exposed to bacterial endotoxin in circulation by administering BPI protein products which bind to and neutralize endotoxin (see, e.g., the Abstract and column 5, lines 4-50). Scott '739 teaches treating a subject suffering from endotoxin-associated shock by administering a BPI protein effective to bind endotoxin (see, e.g., column 4, lines 43-48, and column 7, lines 24-47 and 58-68). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made in the claimed invention of the '199 patent as modified above by Lawrence et al to co-administer the BPI proteins of Friedmann et al or Scott '739 with the activated protein C claimed by the '199 patent because the substitution of one functional equivalent for another is prima facie obvious, because Friedmann et al and Scott '739 teach the use of BPI proteins in treating the same diseases treated by Lawrence et al and by the claims of the '199 patent, and because the BPI proteins of Friedmann et al and Scott '739 can be produced recombinantly and therefore can be relatively cheaply and reliably produced.

7. Claims 16-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,156,734 in view of Lawrence et al. The '734 patent claims treating human patients with an acquired hypercoagulable state, such as sepsis, with human activated Protein C at a dosage rate preferably of about 24 μg/kg/hr for about 24 to about 144 hours. Initial administration can be by bolus injection followed by continuous infusion. The '734 patent does not claim a human activated protein C which is a recombinant human activated protein C. It would have been obvious to one of ordinary skill in the art to use recombinant human activated protein C as the source of the human activated protein C required by the claimed method of the '734 patent because recombinant sources are known, safe, and readily available sources of proteins. The '734 patent does not claim co-administering a BPI protein with the activated protein C. Lawrence et al teach treating Gram-negative bacteremia or septic shock in human patients by administering a combination of a polyclonal immunoglobulin against Gram-negative bacterial endotoxins and protein C. The protein C can be either in its zymogen form or in its activated form. The immunoglobulins and the protein C can be administered either together or separately. The immunoglobulins and the protein C can be administered parenterally, e.g., intravenously, intramuscularly, or intraperitoneally, and the dosages can vary, depending upon disease severity, the status of the patient's hemostatic and fibrinolytic systems, and the use of other active agents. See, e.g., the Abstract; column 4, lines 42-48; and column 5, line 53 - column 6, line 14. The immunoglobulins of Lawrence et al correspond to Applicants' claimed BPI protein. In the specification, Applicants have defined "BPI protein" as embracing polypeptide variants of BPI protein, analogs of BPI protein, and variants of analogs of BPI protein (see, e.g., page 6, lines 30-

37, and page 9, lines 13-29) and emphasize that BPI protein need not have the same or similar amino acid sequence as a natural human BPI protein (see page 9, lines 30-33). At page 2, lines 13-17, of the specification, Applicants state that BPI is capable of binding to and neutralizing lipopolysaccharide/endotoxin, which is the same function exhibited by the immunoglobulins of Lawrence et al. Accordingly, the immunoglobulins of Lawrence et al are deemed to constitute "BPI proteins" as the term is defined by Applicants. It would have been obvious to one of ordinary skill in the art to co-administer the immunoglobulins of Lawrence et al with the human activated protein C claimed by the '734 patent because Lawrence et al teach that co-administration of the immunoglobulins would be effective in treating the underlying infection causing the septic shock. It would have been obvious to one of ordinary skill in the art in the claimed method of the '734 patent as modified above by Lawrence et al to determine all operable and optimal dosages and administration schedules for the co-administered immunoglobulins because dosages and administration schedules are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts, and because Lawrence et al teach the need to optimize dosages and administration schedules depending upon the particular patient being treated.

8. Claims 16-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,156,734 in view of Lawrence et al, Friedmann et al, and Scott '739. Lawrence et al, as applied in the above obviousness-type double patenting rejection, teach administration of an immunoglobulin which binds to and neutralizes lipopolysaccharide/endotoxin, but do not teach administration of BPI which has the same function. Friedman et al disclose treating humans exposed to bacterial

endotoxin in circulation by administering BPI protein products which bind to and neutralize endotoxin (see, e.g., the Abstract and column 5, lines 4-50). Scott '739 teaches treating a subject suffering from endotoxin-associated shock by administering a BPI protein effective to bind endotoxin (see, e.g., column 4, lines 43-48, and column 7, lines 24-47 and 58-68). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made in the claimed invention of the '734 patent as modified above by Lawrence et al to co-administer the BPI proteins of Friedmann et al or Scott '739 with the activated protein C claimed by the '734 patent because the substitution of one functional equivalent for another is prima facie obvious, because Friedmann et al and Scott '739 teach the use of BPI proteins in treating the same diseases treated by Lawrence et al and by the claims of the '734 patent, and because the BPI proteins of Friedmann et al and Scott '739 can be produced recombinantly and therefore can be relatively cheaply and reliably produced.

9. Claims 16-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,489,296 in view of Lawrence et al. The '296 patent claims treating human patients with sepsis using human activated Protein C at a dosage rate preferably of about 24 μg/kg/hr for about 24 to about 144 hours. Initial administration can be by bolus injection followed by continuous infusion. The '296 patent does not claim a human activated protein C which is a recombinant human activated protein C. It would have been obvious to one of ordinary skill in the art to use recombinant human activated protein C as the source of the human activated protein C required by the claimed method of the '296 patent because recombinant sources are known, safe, and readily available sources of proteins. The '296 patent does not claim co-administering a BPI protein

with the activated protein C. Lawrence et al teach treating Gram-negative bacteremia or septic shock in human patients by administering a combination of a polyclonal immunoglobulin against Gram-negative bacterial endotoxins and protein C. The protein C can be either in its zymogen form or in its activated form. The immunoglobulins and the protein C can be administered either together or separately. The immunoglobulins and the protein C can be administered parenterally, e.g., intravenously, intramuscularly, or intraperitoneally, and the dosages can vary, depending upon disease severity, the status of the patient's hemostatic and fibrinolytic systems, and the use of other active agents. See, e.g., the Abstract; column 4, lines 42-48; and column 5, line 53 - column 6, line 14. The immunoglobulins of Lawrence et al correspond to Applicants' claimed BPI protein. In the specification, Applicants have defined "BPI protein" as embracing polypeptide variants of BPI protein, analogs of BPI protein, and variants of analogs of BPI protein (see, e.g., page 6, lines 30-37, and page 9, lines 13-29) and emphasize that BPI protein need not have the same or similar amino acid sequence as a natural human BPI protein (see page 9, lines 30-33). At page 2, lines 13-17, of the specification, Applicants state that BPI is capable of binding to and neutralizing lipopolysaccharide/endotoxin, which is the same function exhibited by the immunoglobulins of Lawrence et al. Accordingly, the immunoglobulins of Lawrence et al are deemed to constitute "BPI proteins" as the term is defined by Applicants. It would have been obvious to one of ordinary skill in the art to co-administer the immunoglobulins of Lawrence et al with the activated protein C claimed by the '296 patent because Lawrence et al teach that co-administration of the immunoglobulins would be effective in treating the underlying infection causing the septic shock. It would have been obvious to one of ordinary skill in the art in the claimed method of the '296 patent as modified above by Lawrence et al to

determine all operable and optimal dosages and administration schedules for the co-administered immunoglobulins because dosages and administration schedules are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts, and because Lawrence et al teach the need to optimize dosages and administration schedules depending upon the particular patient being treated.

10. Claims 16-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,489,296 in view of Lawrence et al, Friedmann et al, and Scott '739. Lawrence et al, as applied in the above obviousness-type double patenting rejection, teach administration of an immunoglobulin which binds to and neutralizes lipopolysaccharide/endotoxin, but do not teach administration of BPI which has the same function. Friedman et al disclose treating humans exposed to bacterial endotoxin in circulation by administering BPI protein products which bind to and neutralize endotoxin (see, e.g., the Abstract and column 5, lines 4-50). Scott '739 teaches treating a subject suffering from endotoxin-associated shock by administering a BPI protein effective to bind endotoxin (see, e.g., column 4, lines 43-48, and column 7, lines 24-47 and 58-68). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made in the claimed invention of the '296 patent as modified above by Lawrence et al to co-administer the BPI proteins of Friedmann et al or Scott '739 with the activated protein C claimed by the '296 patent because the substitution of one functional equivalent for another is prima facie obvious, because Friedmann et al and Scott '739 teach the use of BPI proteins in treating the same diseases treated by Lawrence et al and by the claims of the '296 patent, and because the BPI

proteins of Friedmann et al and Scott '739 can be produced recombinantly and therefore can be relatively cheaply and reliably produced.

11. Claims 16-32 are directed to an invention not patentably distinct from claims 1-16 of commonly assigned U.S. Patent No. 6,008,199. See the above obviousness-type double patenting rejections.

Claims 16-32 are directed to an invention not patentably distinct from claims 1-30 of commonly assigned U.S. Patent No. 6,156,734. See the above obviousness-type double patenting rejection.

Claims 16-32 are directed to an invention not patentably distinct from claims 1-16 of commonly assigned U.S. Patent No. 6,489,296. See the above obviousness-type double patenting rejections.

Commonly assigned U.S. Patent Nos. 6,008,199, 6,156,734, and 6,489,296, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

13. Claims 16-32 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,008,199 in view of Lawrence et al. See the above obviousness-type double patenting rejection.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application of any unclaimed subject matter prior to the effective U.S. filing date of the reference under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

14. Claims 16-32 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,008,199 in view of Lawrence et al, Friedmann et al, and Scott '739. See the above obviousness-type double patenting rejection.

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effective U.S. filing date of the reference under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

15. Claims 16-32 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,156,734 in view of Lawrence et al. See the above obviousness-type double patenting rejection.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application of any unclaimed subject matter prior to the effective U.S. filing date of the reference under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

14. Claims 16-32 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,156,734 in view of Lawrence et al, Friedmann et al, and Scott '739. See the above obviousness-type double patenting rejection.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application of any unclaimed subject matter prior to the effective U.S. filing date of the reference under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

15. Claims 16-32 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,489,296 in view of Lawrence et al. See the above obviousness-type double patenting rejection.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application of any unclaimed subject matter prior to the effective U.S. filing date of the reference under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the

same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

16. Claims 16-32 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,489,296 in view of Lawrence et al, Friedmann et al, and Scott '739. See the above obviousness-type double patenting rejection.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application of any unclaimed subject matter prior to the effective U.S. filing date of the reference under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

17. Instant claims 16-35 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/105,239 because the '239 application, under the test of 35 U.S.C. 112, first paragraph, is deemed to disclose the instant claimed invention. Accordingly, the WO Patent Application 99/20293 is not prior art against the instant claims.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

March 18, 2003